EXHIBIT A

PART I

GENERAL ASSEMBLY

Continued...

for the active operating room, such as those prevalent in pharmacy and clean room settings, should be considered in the future.

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QUESTION 2: Does the use of forced air warming (FAW) during orthopaedic procedures increase the risk of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: There is no evidence to definitively link FAW to an increased risk of SSIs/PJIs. Alternative methods of warming can be effective and may be used.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 93%, Disagree: 2%, Abstain: 5% (Super Majority, Strong Consensus)

RATIONALE

Maintaining intraoperative normothermia has been shown to reduce perioperative complications including SSI. FAW represents one of the most widely-used methods to prevent hypothermia and maintain intraoperative normothermia. Intraoperative hypothermia has been linked to increased mortalities and morbidities, longer hospital stays, increased requirements for blood transfusion and increased SSI rates. The SSI prevention effects have not been demonstrated in implant surgery, such as total knee arthroplasty (TKA), total hip arthroplasty (THA) and total shoulder arthroplasty (TSA). There has been a concern in the literature about possible contamination of the operating room (OR) air and surgical field with these devices, and subsequent potential increased risk of SSI, especially PJI. Conductive fabric blankets (CFBs) have been suggested as an alternative for intraoperative warming.

Several experimental studies raised a concern for the possibility of intraoperative contamination caused by FAW. McGovern et al. compared FAW and conductive fabric warming (CFW) devices in a simulation of hip and spine surgery with a mannequin used as a patient [1]. They used bubbles generated at the floor and at the mannequin's head to monitor flow of air in the simulated theater and detected significantly increased bubbles close to the surgical field with the use of the FAW devices. They also conducted a clinical review of their infection data between a twenty-month period when FAW devices were used vs. a seven-month period where CFW devices were used, and found a statistically higher rate of deep SSI with the use of the FAW device. The authors noted, however, that their observational study did not account for infection control procedures that changed over the study period or account for several possible differences in patient risk factors, such as obesity and fitness for surgery. Other studies of the same cohorts by these researchers revealed potential impacts unrelated to the change in warming modality, including thromboprophylaxis [2] and methicillin-sensitive *Staphylococcus aureus* screening [3]. Legg et al. measured changes in temperature and air particles at the surgical site in a simulated OR setup with a volunteer patient simulator [4]. They found statistically significant increases in temperature and particle counts with the

use of FAW compared to controls or radiant warming devices. In a follow-up study on a simulated TKA set-up, the authors used a bubble generator with a digital camera to actually visualize airflow disruptions caused by FAW [5].

Similar to the prior study, they showed a significant increase in particle counts at the surgical site and in drape temperatures. They also identified a substantial disruption in the unidirectional airflow when FAW was used. Dasari et al. conducted an experiment where a mannequin was used as a patient and temperature was measured at multiple different heights and locations with the use of FAW, a conductive blanket or a resistive mattress [6]. They found significantly greater temperature increases caused by FAW at patient height locations, whereas, temperatures measured at other heights (floor, head and ceiling) were similar among the three warming devices. They concluded that FAW generates convection current activity in the vicinity of the surgical site which may disrupt laminar air flow. Belani et al. conducted a study with a mannequin draped for a TKA in an orthopaedic room and a bubble generator placed at the head to visualize air currents [7]. Bubbles were counted on sequential photographs at the surgical field and compared between FAW and CFW. The authors found significantly increased bubble counts over the surgical site with FAW and time-lapse photography identified convection currents mobilizing air from the mannequin's head over the drapes and into the surgical field. A recent predictive fluid flow simulation conducted by He et al. on a computer aided design OR showed significant disruption in airflow caused by FAW with a displacement of squames from the floor into the surgical field [8].

Tumia et al. quantified bacterial counts in air samples taken in empty ORs, during normal surgical operations prior to turning the FAW device on, and 15 minutes after turning the warmer on [9]. They had low study numbers to reach statistical significance, but they observed an increase in bacterial counts during regular surgical operations with the warmer off compared to the empty OR and a further increase after turning the warmer on. They concluded that most of the contamination of OR air is secondary to the presence of surgical staff and OR traffic, and that FAW increases contamination to a lesser extent, but this is likely not of clinical significance given that the counts seen were still well below recommendations for ultra-clean air theaters. Albrecht et al. evaluated filter efficiency in the air blower of FAW devices and found that the intake filters used in air blowers were far from optimal efficiency which resulted in colonization of the internal parts of the device [10,11]. They cultured organisms such as *Staphylococcus aureus* and coagulase-negative *Staphylococcus*, which are known to be the major pathogens in total joint arthroplasty. Avidan et al. sampled air coming out of blowers and also found positive cultures in 4 out of 10 devices [12]. However, after connecting the perforated blanket to the air blower and sampling the air coming out underneath the blankets, no organisms grew.

On the other hand, several studies have failed to demonstrate any increased contamination with the use of FAW. Sharp et al. performed a surgical simulation using patients with psoriasis, who are known to have increased shedding of skin [13]. They utilized slit-air sampling and simulated regular OR activity. No bacterial colonies were grown, leading the authors to conclude that FAW did not result in the contamination of the surgical site. Sessler et al. evaluated the effect of FAW on operative room air in laminar airflow conditions using volunteer subjects in an OR with simulated surgical set-up and heated mannequins to simulate OR personnel [14]. A smoke plume was used to visualize airflow and revealed that FAW did not induce any upward draft or any disruption in the normal downward movement of sterile air. A particle counter was used to evaluate changes in particle concentrations near a theoretical incision site. No significant differences were found between having the FAW device off, on ambient air or on warm air. All scenarios had particle counts below stringent criteria established in Europe for the evaluation of adequate function of laminar flow in operating rooms.

Moretti et al. evaluated the effect of FAW on air quality during THA procedures with the use of an air-sampling device with agar plates [15]. No differences in bacterial loads were noted at several positions of the surgical field with or without the use of FAW. Memarzadeh et al. reported computational fluid dynamics and particle tracking studies conducted by the National Institutes of Health to assess whether FAW devices lead to contamination of the surgical site [16]. They found no increased squame deposition from potential contaminant sources due to the FAW device in laminar flow theater situations in their models. Zink et al. evaluated air quality in rooms with volunteers lying down covered by surgical drapes with culture plates placed on their abdomen while FAW was turned on for two hours [17]. Results were compared to a two-hour period where the warmer was turned off. No statistically significant difference was identified between the two situations. Shirozu et al. looked at the effect of FAW on airflow in a simulated operative setting with the use of an ultrasonic anemometer, smoke and laser light [18]. The authors found that downward laminar flow efficiently counteracted the upward airflow caused by FAW blankets and concluded that contamination of the surgical field is not likely in the presence of adequate laminar flow. In a study from the veterinarian literature, two groups of surgical patients were compared (one with use of FAW blankets and one without) [19]. Surgical drapes were swabbed and aerobic cultures were obtained. No difference in positive cultures was noted.

Oguz et al. recently conducted a prospective study where orthopaedic patients were randomized to receive either a FAW blanket or a CFW [20]. They performed a multivariate analysis looking at the effect of multiple factors on the number of bacteria in the OR air and on the field as measured by agar plates positioned at different locations in the room, and nitrocellulose plates placed on the instrument table. These factors included the type of warming device in addition to the presence of laminar airflow, the number of operating room personnel and the operative time. While increased surgical time and absence of laminar flow significantly affected bacterial counts, the type of warming device used did not.

Sikka and Prielipp published a focused review of the literature in the Journal of Bone and Joint Surgery and concluded that there is not enough evidence to support or disprove a link between FAW and PJI [21]. They did list recommendations that need to be followed for proper use of the devices including frequent filter changes, calibration and always using the device with the accompanying blanket. Kellam et al. in a comprehensive review for the Association of Perioperative Registered Nurses (AORN) failed to identify conclusive evidence for an increased risk of SSI with the use of FAW and recommended continued use of these devices [22]. Wood et al. conducted a similar review and concluded that FAW does contaminate ultra-clean air in the operating room, but found no definite link to an increased rate of SSIs [23]. They recommended considering alternative warming systems when contamination of the surgical field is deemed to be critical. In a more recent systematic review that encompassed a total of 1,965 patients and 8 studies, Haeberle et al. concluded that there was an absence of evidence to support an increased rate of SSI with the use of FAW blankets [24].

Sandoval et al. compared FAW vs. CFW in its ability to prevent hypothermia in 120 THA and TKA surgeries [25]. There were 60 patients in each group and they concluded that FAW and CFB were equally as effective at maintaining core temperatures during and after surgery. There were no reported SSIs in either group. This study was a quality improvement project and not powered to show a clinically significant difference in infection rates.

In conclusion, the literature is conflicting and there is still a lack of strong evidence linking FAW to increased risk of SSI. In light of this, while we recognize the theoretical risk posed by FAW, we cannot recommend discontinuing the use of these devices at this time. We do, however, recommend following the manufacturer's instructions and frequently changing the filters, making sure the devices are calibrated and most importantly using the devices only with the appropriate perforated blanket. Other alternative warming methods can be used. We recommend a randomized prospective trial to answer the index question, and a pilot is underway. (ISRCTN 74612906)

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QUESTION 3: Does the operating room (OR) temperature affect the rate of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: The OR temperature may affect core body temperature, which could potentially affect the rates of subsequent SSIs/PJIs. Thus, all efforts should be made to maintain an optimal OR temperature.

LEVEL OF EVIDENCE: Consensus

DELEGATE VOTE: Agree: 88%, Disagree: 8%, Abstain: 4% (Super Majority, Strong Consensus)

RATIONALE

Multiple OR varaibles are known to influence the rates of SSIs/PJIs in patients undergoing orthopaedic procedures. Some of the important issues in the OR are the status of the ventilation system, environmental contamination, including air as well as surface contamination in association with humidity, and temperatures that are known factors sustaining microorganism growth. Clinically used ventilation systems are able to reduce the number of colony forming units (CFUs) near the surgical field. However, systems using vertical laminar airflow and those relying on a newly developed temperature-controlled air flow have been shown to achieve better suppression of environmental contamination that is even more efficacious than classical laminar air flow systems.

Recently-published studies have demonstrated correlations between seasonal temperature changes and SSI rates. SSIs peaked during the warmer season and were lowest in the winter and this in itself could include a multitude of additional environmental factors.

The currently-available literature has not established the ideal OR temperature range, but suggests that temperatures around or below 24°C are preferable. In some countries (e.g., Germany), International Organization for Standardization (ISO) norms describe a

need to select OR temperatures between 18°C and 24°C. We are not aware of any studies about a lower temperature boundary showing adverse effects concerning wound healing, cardiovascular circulation, etc.

Another factor associated with increased temperatures in the OR setting are the increase in transpiration rates among the OR personnel, specifically the surgeon, who may contaminate the surgical field with sweat.

Everett et al. reported that the incidence of SSIs increased when the ventilation system progressively deteriorated. They found with new improved ventilation systems the infections returned to baseline rates. The control of temperature and humidity is important mainly for the comfort of the OR personnel (low-quality study) [1].

Alfonso-Sanchez et al. conducted a longitudinal prospective study to identify the influence of OR environmental factors on subsequent SSIs. Risk factors related to the OR included the level of fungi and bacterial contamination, temperature and humidity, as well as air renewal and differential air pressure. Patient-related variables assessed included age, sex, comorbidities, nutrition level and transfusion. Other factors were antibiotic prophylaxis, electric versus manual shaving, American Society of Anaesthesiologists physical status classification, type of intervention, duration of the intervention and preoperative stay [2]. Superficial SSIs were most often associated with environmental factors, such as environmental contamination by fungi (from two colony-forming units), by bacteria, as well as surface contamination. The environmental factors studied, including the OR temperatures, were found to influence the rates of subsequent SSIs. For example, when there was no contamination in the OR, no SSIs were detected. Significant risk factors in superficial SSIs were environmental contamination by fungi (≥ 6 CFU/m³, with a relative risk (RR) of 6.2), bacteria, as well as surface contamination by both fungi and bacteria. Also important were humidity, differential pressure and OR temperatures. The OR temperature was associated with superficial SSIs, but not deep SSIs [2].

Fu Shaw et al. noted that the bacterial colony count increased by 9.4 CFU/m³ with each additional 1°C rise at room temperature ($p = 0.018$) [3]. Another study by Alsved et al. compared two commonly-used ventilation systems (vertical laminar airflow (LAF) and turbulent mixed airflow (TMA)) with a newly-developed ventilation technique and temperature-controlled airflow (TAF), measuring CFU concentrations at three OR locations. They also evaluated comfort on the operating team. The study found that only LAF and TAF resulted in less than 10 CFU/mL at all measurement locations in the room during surgery. Median values of cfu/m³ close to the wound (250 samples) were 0 for LAF, 1 for TAF and 10 for TMA. Peripherally in the room, the CFU concentrations were lowest for TAF. The CFU concentrations did not scale proportionally with airflow rates. Compared with LAF, the power consumption of TAF was 28% lower and there was significantly less disturbance from noise and draught. [4].

Anthony et al. analyzed 760,283 procedures (total knee arthroplasty (TKA) 424,104, total hip arthroplasty (THA) 336,179) for the influence of seasonal temperatures on SSIs. Their models indicate that SSI risks were highest for patients discharged in June, and lowest for those discharged December. For TKA, the odds of 30-day readmission for SSIs were 30.5% higher at the peak compared to the nadir time (95% confidence interval (CI) 20 to 42). For THA, the seasonal increase in SSIs was 19% (95% CI 9 to 30). (High-quality study) [5].

Another study by Anthony et al. described a highly seasonal variability of SSI, with the highest SSI incidence in August and the lowest in January. During the study period, there were 26.5% more cases in August than in January (95% CI, 23.3 to 29.7). Controlling for demographic and hospital-level characteristics, the odds of a primary SSI readmission increased by roughly 2.1% per 2.8°C (5°F) increase in the average monthly temperature. Specifically, the highest temperature group (> 32.2°C [> 90°F]) was associated with an increase in the odds for an SSI readmission by 28.9% (95% CI, 20.2 to 38.3) compared to lower temperatures (< 4.4°C [< 40°F]) (moderate-quality study) [6].

Mills et al. concluded that the sweating surgeon may most likely contaminate the surgical field as a result of elevated OR temperatures [7].

Based on the available evidence, it appears that OR tempreature is an important enviromental factor that needs to be optimally controlled during surgical procedures. There is an indirect link between the OR temperatures and the potential for subsequent SSIs/PJIs.

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QUESTION 4: Does perioperative normothermia affect the rate of subsequent surgical site infections/periprosthetic joint infections (SSIs/PJIs)?

RECOMMENDATION: Based on data from general surgery and other surgical disciplines, normothermia has been found to be an important factor during the perioperative period, in order to minimize the risks of subsequent infections. Although evidence in orthopaedic surgery is sparse, we recommend that normothermia also be maintained in patients undergoing orthopaedic procedures.

LEVEL OF EVIDENCE: Limited

DELEGATE VOTE: Agree: 97%, Disagree: 1%, Abstain: 2% (Unanimous, Strongest Consensus)

RATIONALE

Medications used during general anesthesia, such as inhaled and intravenous agents as well as opioids, alter the ability for the body to thermoregulate which may result in hypothermia [1]. Hypothermia can also result from the use of neuraxial anesthesia, except with peripheral nerve blocks [1]. Several animal studies have demonstrated that intraoperative hypothermia may decrease resistance to some pathogens, such as *Escherichia coli* (*E. coli*) and *Staphylococcus aureus* [2,3]. Hypothermia and secondary vasoconstriction may also lead to reduced oxygen delivery to tissues, increasing the risks of infectious complications [4–6]. Several well-designed studies have attributed a substantial decrease in SSI rates in colorectal and non-orthopaedic clean surgeries with normothermia [5,6]. Therefore, current guidelines from the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) recommend maintaining perioperative normothermia to reduce the risk of SSIs and other complications associated with surgery [7,8]. However, there is a paucity of published literature regarding normothermia in orthopaedic procedures.

In a recent observational study evaluating the role of hypothermia in hip fractures, the incidence of perioperative hypothermia was 17%. After multivariate logistic regression analysis, hypothermia was associated with increased risk of periprosthetic joint infection (PJI) (odds ratio (OR): 3.30, 95% confidence interval (CI) 1.19 to 9.14, p = .022) [9]. In contrast, from another observational study evaluating total hip and knee arthroplasties, no statistically significant associations were found between hypothermia and PJIs or SSIs in univariate analysis [10]. Observational studies [10–13] have associated hypothermia with increased blood loss and transfusion rates, which may subsequently lead to increased risks for PJIs or SSIs. However, there are no randomized controlled trials (RCTs) that support nor discourage normothermia in total joint arthroplasty (TJA) or other orthopaedic procedures in relation to SSIs or PJIs.

There are several RCTs that have been performed outside of orthopaedics, which support the use of warming devices in the operating room and during the surgical procedure for the purposes of reducing SSIs [5,6]. Kurz et al. evaluated the importance of maintaining perioperative normothermia with additional warming in major colorectal surgery patients [5]. The mean final intraoperative core temperature was higher in those with additional warming compared with those without (36.6 vs. 34.7 °C, p < 0.001). Patients assigned to additional warming demonstrated a significant decrease in SSI rates by receiving forced-air warming blankets combined with fluid warming (6 vs. 19%, p = 0.009). In another RCT, Melling et al. evaluated patients undergoing non-orthopaedic clean surgeries and identified a substantial role of pre-warming in preventing SSI [6]. They showed that warming the patient for at least 30 minutes before surgery led to a reduction in infection rate from 14 to 5% (p = 0.001) [6].

The safest and most effective mode of maintaining intraoperative normothermia remains unknown. Some recent studies have raised potential issues with the use of forced-air warming systems that may disrupt the laminar airflow (LAF) in operating rooms and increase risks for SSIs [14–16]. But, from a recent experimental study, disruption of airflow produced by forced-air warming was well-counteracted by downward LAF from the ceiling [17]. There are no studies which provide high-level evidence that warming systems may increase infection rates.

In summary, achieving normothermia by using warming devices in the operating room and during the surgical procedure seems to play an important role in decreasing the risks of subsequent infections. However, this evidence mainly derives from non-orthopaedic literature. Further research is needed to establish correlation between patient's temperature and SSIs in the field of orthopaedic surgery, including TJAs.

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EXHIBIT B

Proceedings of the Second International Consensus Meeting on Musculoskeletal Infection

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Javad Parvizi, MD, FRCS
Thorsten Gehrke, MD

Published by
Data Trace Publishing Company
P.O. Box 1239
Brooklandville, Maryland 21022-9978
410-494-4994 Fax: 410-494-0515
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This document on the prevention, diagnosis and treatment of orthopaedic infections is compiled as a result of work of over 800 individuals from around the globe. It is important to note that the text for each question has been composed by individual experts in each field. It is certainly possible that key studies have been overlooked, some points may be emphasized more than other points and each section may suffer from potential individual biases. Nevertheless, the responses to each question have been scholarly researched, evaluated by the majority of the delegates and discussed and voted on during the face-to-face meeting in Philadelphia.

It is important to note that each section does not necessarily represent the personal opinions of Drs. Parvizi and Gehrke, or any individual participating in the Consensus. Therefore, the document should not be interpreted as definitive or in fact represent the "standard of care." The experts who committed innumerable hours to generate this document have done so in the hopes of improving patient care.

ISBN: 978-1-57400-157-0

We wish to thank the
Orthopaedic Research and Education Foundation
and the
American Association of Hip and Knee Surgeons
for their generous support and for allowing the
publication of the consensus material.

Foreword

The English dictionary defines consensus as a "general agreement about something." It is seen as the middle ground in decision-making, between total assent and total disagreement. The process of consensus depends on the participants having shared values and common goals. A consensus leads to the generation of an agreement on specific issues that provide overall direction for the future. The Second International Consensus Meeting (ICM) on orthopaedic infections had the above objectives in mind. The second meeting was built on the success of the first ICM meeting that was held in 2013 and implemented additional steps, based on the input of the delegates from the prior meeting, with the intention of improving the outcomes.The second ICM meeting was different in three aspects:

1) It included delegates from all subspecialties of orthopaedics including: Hip and Knee Arthroplasty; Foot and Ankle; Oncology; Pediatrics; Shoulder; Elbow; Spine; Sports; and Trauma.
2) The consensus was conducted according to the Delphi method again (see below). However, this time instead of having a central group conduct the research and write out the recommendations and rationale for each question, individual delegates were engaged. For each question, the delegates evaluated the available literature, extracted the evidence for current practices and identified the areas in need of further research. The level of evidence related to each "recommendation" was also identified. To the best of our knowledge, no published work related to orthopaedic infections was missed.
3) The meeting allowed for the participation of representatives from governmental organizations, payers and business administrations. Although these participants were not allowed to vote in the process, their presence was deemed to be important in developing the road map for funding, supporting and approving technologies related to orthopaedic infections in the future.

The name Delphi derives from the Oracle of Delphi and was developed in the beginning of the Cold War to forecast the impact of technology on warfare. General Henry H. Arnold had ordered the creation of a report for the United States Army Air Corps on technological capabilities that could be used in future warfare. Very soon it became apparent that forecasting methods, technological approaches and quantitative models could not be used, as little "scientific evidence" had been published in this field. To overcome these limitations, the Delphi method was developed by Project RAND during the 1950s and 1960s [1]. The Delphi method continues to be used by the military today and has found its way into the scientific and medical communities [2].

The exact description of the Delphi method that was utilized in the first ICM meeting has been previously published [3] and the document or executive summaries have been published in various venues [4–6]. The second ICM meeting also followed similar steps, with every step of the process being supervised by Dr. William Cats-Baril. The seed for the second consensus meeting was set in soil in June of 2016 when, at the request of many experts from around the world, we decided to proceed. Thirteen specific steps were followed.

Step 1 (August 2016 to December 2016): **Selection of Delegates.** This step aimed to gather the experts from around the globe, with no country overlooked, who could lend their expertise to the consensus process. The delegates were identified based on their publication track record in the field (at least five publications within the last five years), specialty society nominations or their clinical expertise (high volume) in taking care of patients with orthopaedic infections. The search identifed 953 delegates who were sent invitations. Some of the delegates did not respond to the invitation (63) or declined to participate (21), leaving 869 potential delegates to participate.

Step 2 (December 2016 to April 2017): **Identification of Issues.** The delegates were then asked to send in 5 to 10 questions (issues) in the field of orthopaedic infections that they felt needed to be explored. A total of 3,210 questions were received.

Step 3 (April 2017 to August 2017): **Ranking of Questions.** The collected questions were then sent to the delegates again and they were asked to prioritize them. In this process, we did not deliberately remove duplicate questions and did not make any changes to the "writing" of the questions. We believed that "duplications" perhaps represented the higher priority of a question.

Step 4 (August 2017 to November 2017): **Evaluation of Ranked Questions.** Once the ranking had been received, the duplicate questions were removed, and the stem of each question was rewritten according to the Delphi method. This step was necessary to remove "suggestive" phrases such as "what is the role of…?" as opposed to "is there a role…?" This left us with 652 questions that comprised the final set of questions to be explored.

Step 5 (December 2017): **Assignment of Questions.** The final set of questions were then assigned to at least two delegates per question based on the publication track record of the delegate or the desire of a delegate to research a specific question. The delegates were given specific instructions on how to conduct research on the topics presented in each question and how to write up the responses.

Step 6 (December 2017 to March 2018): **Systematic Review.** During this time period, the delegates were actively engaged in researching a specific question and preparing the preliminary document related to each question. The two delegates assigned to each question worked independently for all orthopaedic specialties except for the Shoulder group who decided to work together. No published works in the English language were meant to be missed during this process.

Step 7 (February 2018 to April 2018): **Interdelegate Discussions.** The document received from one delegate was then sent to the other and both delegates were made aware of each other's write up and research. The activity was coordinated centrally to create one document that was acceptable by both delegates. Over 6,000 emails were exchanged during this process alone.

Step 8 (April 2018 to May 2018):**Document Merging/Editing.** All received documents were reviewed, write-ups checked to remove plagiarism, references updated and the English language edited.
Step 9 (June 2018 to July 2018): **Document Evaluation by all Delegates.** Although the documents generated were posted on the website (www.ICMPhilly.com) for many months and available for view by EVERYONE (including the public), the final document was sent to the delegates and they were asked to review any and all questions that were posted live on the website. We received numerous comments from delegates during this period and implemented any and all appropriate changes to the document prior to the meeting.

Step 10 (July 2018): **Final Pre-Meeting Review/Editing.** The entire document was reviewed by the internal editorial team and some additional changes were made. The latest publications, up until June 30, 2018, were also checked and added to relevant sections.

Step 11 (July 25–26, 2018): **Pre-Vote Discussion.** All delegates who traveled to Philadelphia met in their workgroups and discussed some of the questions in their fields. The questions were divided into four categories: 1) Highly clinically relevant with little evidence supporting the recommendation; 2) Highly controversial and clinically relevant; 3) Highly relevant and with great supportive evidence for the recommendation; and 4) Not clinically highly relevant with or without supportive evidence. During the meeting, questions from categories 1 and 2 were discussed.

Step 12 (July 27, 2018). **Voting.** All questions were presented on a screen and the delegates were allowed to vote in real time. The result from voting appeared on the screen shortly after the vote. There were three possible responses to each recommendation: agree; disagree; or abstain. The process of voting was clearly explained by Dr. William Cats-Baril to the delegates prior to voting.

Step 13 (August 2018 onwards): **Dissemination of Consensus Document.** Following the meeting, the voting results were implemented into the document. The document was additionally reviewed by outside editors of Journals, in particular by Dr. Michael A. Mont and his fellow, Dr. Nipun Sodhi, Dr. Thomas Bauer and Dr. Adolph J. "Chick" Yates. The delegates were given the opportunity to review the final document over a four-week period and to provide any additional feedback. All suggested and appropriate changes were implemented into the document. The final document was then sent to various journals for publication as well as for publication in a consolidated book form. The final document is also being translated into different languages.

As can be seen from the above, the delegates were very engaged at every step of the way in generating the consensus document. It is clear, however, that a complex process, like the above, may fall victim to some shortcomings and errors. We made every effort to minimize those as much as possible. We also attempted to be inclusive of all experts from around the world. We are certain that we may have missed some very deserving experts who should have been part of this process. We apologize in advance to any experts who were missed, to the readers who may have to endure some errors in the document, to the authors of reports who may have been missed unintentionally and to anyone else who may feel perturbed because of our shortcomings. We hope that the document that is generated will serve the orthopaedic community for years to come and improve the care of our patients.

Javad Parvizi, MD

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Acknowledgments

A feat of this grandeur cannot happen without the selfless sacrifices of many. The delegates and their coauthors from around the world should be congratulated for producing a unique and useful document that will serve patients for years to come. Their dedication, commitment and passion are very much appreciated. Special thanks to **Tiffany Morrison** who was, without a doubt, THE most critical person for the success of this meeting. Her dedication and the endless efforts to take care of every detail is beyond description. **Allie Martin,** a name recognized by us all, shepherded the effective and timely communications over the two years leading up to the final document, working selflessly to ensure that all the ducks were in a row at all times. Thanks to the **Editorial Team** who read and edited the document numerous times prior to the meeting in order to ensure accuracy and to produce a comprehensible text. Thanks to **Willy Cats-Baril**, the true maestro of the consensus, who kept our feet to the fire at all times ensuring that we complied with the Delphi process, and who beautifully orchestrated the face-to-face meeting. Our gratitude to **Ali Kasemkhani**, our in-house dentist and artist who lent us his artistic expertise in creating the logo, generated visual documentations of the meeting and added many other fine touches to the meeting. We wish to thank our **Industry Partners** for their commitment to our profession and their desire to continuously improve the lives of our patients through innovative tools, techniques and medicines. Their financial support was critical to the success of this meeting and to that we owe them our immense gratitude.

Finally, we want to thank our **wives and children** who allowed us to steal valuable time away from them over the past two years in order to work on the consensus. They were also actively engaged in organizing the social event that generated a successful conclusion to the meeting.

Editorial Board

Special thanks to Dr. Michael A. Mont and his fellow, Dr Nipun Sodhi, who read through the entire document after the July meeting, investing numerous hours editing and checking for accuracy and completeness. We are truly grateful to both of them. Our gratitude also goes out to Dr. Thomas Bauer and Dr. Adolph J. "Chick" Yates, who also spent many hours reading and editing the post-vote document.

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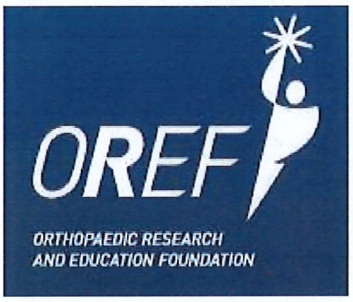

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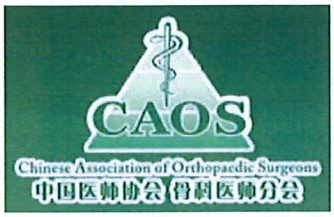
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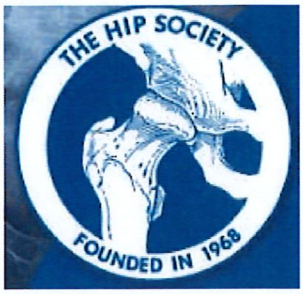
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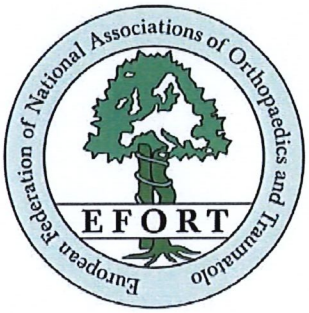
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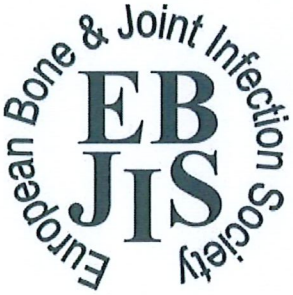
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Pachore, Javahir
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Schwarz, Edward
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Jones, Stephen
Morgan-Jones, Rhidian

Yemen
Binlaksar, Ruwais

EXHIBIT C

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	File No. 15-MD-2666 (JNE/FLN)
	August 18, 2016
	Minneapolis, Minnesota
	Courtroom 12W
	2:14 p.m.

BEFORE THE HONORABLE JOAN N. ERICKSEN
UNITED STATES DISTRICT COURT JUDGE

And THE HONORABLE FRANKLIN D. NOEL
UNITED STATES MAGISTRATE JUDGE

(STATUS CONFERENCE)

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(Appearances continued next page)

and that sort of thing.

MAGISTRATE JUDGE NOEL: Okay. Let me just make sure I understood what you just told me. If there is a resolution of this issue regarding custodians, and I'm not sure I fully understand exactly how that issue would be framed. But if that issue is resolved, most of these 90-plus line items in the chart would go away?

MS. ZIMMERMAN: I think that's correct, Your Honor.

MAGISTRATE JUDGE NOEL: Okay. Okay, thank you.

THE COURT: Could I just reframe that so I understand it, just to make sure I understand. You have been receiving documents from 3M responsive to these 90-plus other requests, right?

MS. ZIMMERMAN: To some of them, yes.

THE COURT: And you're just not sure if they're looking in all the right places?

MS. ZIMMERMAN: Correct.

THE COURT: And you think it's not your job to identify the custodians. It's your job to identify the information that you want.

MS. ZIMMERMAN: Correct.

THE COURT: And it's their job to look for it.

MS. ZIMMERMAN: Correct.

THE COURT: And because you've had a somewhat